4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality (OPQ) has modified its organizational structure. This new structure was approved by the Secretary of Health and Human Services on August 10, 2023.

FOR FURTHER INFORMATION CONTACT: Michael Kopcha, Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993, 240-402-2461.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect reorganization of CDER, OPQ.

This reorganization changed the OPQ organizational structure from an office with nine suboffices to 10 suboffices. The former offices with divisions and branches had their branches abolished and the branch functions and resources were realigned to their respective divisions.

The OPQ retitled four of its suboffices and retitled the majority of its divisions. The OPQ will establish the Office of Quality Assurance and within it established the Quality Assurance Staff, Learning and Professional Staff, and the Project Management Staff.

FDA, CDER, OPQ has been restructured as follows:

DCDL. ORGANIZATION. The Office of Pharmaceutical Quality is headed by the Director of Pharmaceutical Quality and includes the following organizational units:

Office of Pharmaceutical Quality (DCDL)

Office of Product Quality Assessment I (DCDLH)

Division of Product Quality Assessment I (DCDLHA)

Division of Product Quality Assessment II (DCDLHB)

Division of Product Quality Assessment III (DCDLHC)

Division of Product Quality Assessment IV (DCDLHD)

Division of Product Quality Assessment V (DCDLHE)

Division of Product Quality Assessment VI (DCDLHF)

Office of Product Quality Assessment II (DCDLB)

Division of Product Quality Assessment VII (DCDLBA)

Division of Product Quality Assessment VIII (DCDLBB)

Division of Product Quality Assessment IX (DCDLBC)

Division of Product Quality Assessment X (DCDLBD)

Division of Product Quality Assessment XI (DCDLBE)

Division of Product Quality Assessment XII (DCDLBF)

Office of Product Quality Assessment III (DCDLA)

Division of Product Quality Assessment XIII (DCDLAA)

Division of Product Quality Assessment XIV (DCDLAB)

Division of Product Quality Assessment XV (DCDLAC)

Division of Product Quality Assessment XVI (DCDLAD)

Division of Product Quality Assessment XVII (DCDLAE)

Division of Product Quality Assessment XVIII (DCDLAF)

Division of Product Quality Assessment XIX (DCDLAG)

Office of Pharmaceutical Manufacturing Assessment (DCDLD)

Division of Pharmaceutical Manufacturing Assessment I (DCDLDA)

Division of Pharmaceutical Manufacturing Assessment II (DCDLDB)

Division of Pharmaceutical Manufacturing Assessment III (DCDLDC)

Division of Pharmaceutical Manufacturing Assessment IV (DCDLDD)

Division of Pharmaceutical Manufacturing Assessment V (DCDLDE)

Division of Pharmaceutical Manufacturing Assessment VI (DCDLDF)

Office of Program and Regulatory Operations (DCDLG)

Division of Regulatory & Business Process Management I (DCDLGA)

Division of Regulatory & Business Process Management II (DCDLGB)

Division of Regulatory & Business Process Management III (DCDLGC)

Division of Regulatory & Business Process Management IV (DCDLGD)

Office of Pharmaceutical Quality Research (DCDLF)

Division of Pharmaceutical Quality Research I (DCDLFA)

Division of Pharmaceutical Quality Research II (DCDLFB)

Division of Pharmaceutical Quality Research III (DCDLFC)

Division of Pharmaceutical Quality Research IV (DCDLFD)

Division of Pharmaceutical Quality Research V (DCDLFE)

Division of Pharmaceutical Quality Research VI (DCDLFF)

Office of Policy for Pharmaceutical Quality (DCDLC)

Compendial Operations and Standards Staff (DCDLCA)

Division of Regulations and Guidance (DCDLCB)

Division of Internal Policy and Communication (DCDLCC)

Division of Editorial and Project Management (DCDLCD)

Office of Quality Assurance (DCDLJ)

Quality Assurance Staff (DCDLJ1)

Learning and Professional Development Staff (DCDLJ2)

Enterprise Project Management Staff (DCDLJ3)

Office of Quality Surveillance (DCDLE)

Division of Quality Intelligence I (DCDLEB)

Division of Quality Intelligence II (DCDLEC)

Division of Quality Intelligence III (DCDLED)

Office of Administrative Operations (DCDLI)

Administrative Analysis Staff (DCDLI1)

Administrative Operations Staff 1 (DCDLI2)

Administrative Operations Staff 2 (DCDLI3)

Administrative Operations Staff 3 (DCDLI4)

Administrative Operations Staff 4 (DCDLI5)

Financial Services Staff (DCDLI6)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm

(Authority: 44 U.S.C. 3101).

Xavier Becerra,

Secretary of Health and Human Services.

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